K061827

AUG - 4 2006

510 (k) Summary for the SONIX Ultrasound Scanner

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Devices Act of 1990 revisions to 21 CFR, Part 807.92, Content and format of a 510(k) summary.

1.0 Submitter Information

1.1 Submitter

Ultrasonix Medical Corporation
301-3480 Gilmore Way
Burnaby, British Columbia
Canada V5G 4Y1
(t) 604-437-9500
(f) 604-437-9502

1.2 Contact

Iulia Nuca, QA Manager
(t) 604-437-9500 x 105
(f) 604-437-9502
(e) **iulia@ultrasonix.com**

1.3 Date Prepared

June 26, 2006

2.0 Device Name

2.1 Common Name

Ultrasound Imaging System

2.2 Proprietary Name

Sonix Ultrasound Scanner

2.3 Classification Name

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

2.4 Classification

Class IIa

2.5 Predicate Device:

Ultrasonix Ergosonix 500 Ultrasound Scanner (K020630)
ATL HDI 5000 System (K002003)
Acuson Sequoia (K973767)

2.6 Reason for submission:

Clearance request for:

- **UPS**
- **Wireless**
- **Barcode reader**
- **Data Management for ultrasound QA**
- **The intended use of biopsy:**

Transducers: L9-4/38
L14-5/38
L14-5W/60
C5-2/ 60
EC9-5/10
C7-3/50

Name change request

N/A

New product clearance

N/A

2.7 Device description

The Sonix Ultrasound Scanner is a highly mobile, software-controlled, diagnostic ultrasound system capable of the following operating modes: 2D B-mode, M, Pulsed and CW Doppler, Color Flow (including amplitude Doppler). The system can generate real-time compound images and harmonic images.

The system has an electrocardiography (ECG) display feature and support a 3-lead ECG cable assembly. The systems provide measurement capabilities for anatomical structures and fetal biometry that provide information used for clinical diagnostic purposes. The system has a PA and CW audio output feature and cine review, image zoom, labeling, biopsy, measurements and calculations, image storage and review, printing, and recording capabilities. The systems include a Digital Imaging and Communications (DICOM) module which enables storage.

The system is designed for use in linear, convex and phased array scanning modes, and supports linear, convex, microconvex and phased array probes.

The biopsy kits are accessories to the Sonix Ultrasound Scanner. These accessories are made up of a polymeric bracket. There are features on the bracket that prevent the bracket from being oriented incorrectly when attached to the transducer. The brackets are not sterile and will be covered with a sterile sheath prior to use. These brackets are designed to accept and retain the needle guides in a mechanically secure way through the medium of the sterile sheath. The brackets are reusable. The needle guide is a separate sterile polymeric part that attaches to the bracket through a sterile sheath. The needle guides will support various sized needles. The needle guides are sold in sterile kits that contain multiple needle guides, sterile sheaths, ultrasound transmission gel, and bands. The needle guides are single use (disposable).

Frequency Range	2-15MHz
Transducer types	Linear array Curved array Intracavity array Phased array

The Sonix Ultrasound Scanner is designed to comply with the following standards:

EN 60601-1	European Norm, Medical Electrical Equipment
UL 2601-1	Underwriters Laboratories Standards, Medical Electrical Equipment
C22-2 No 601-1	Canadian Standards Association, Medical Electrical Equipment
EM 60601-1-1-2	European Norm, Collateral Standard, Electromagnetic Compatibility
IEC 60601-2-37	Particular requirements for the safety of ultrasonic medical diagnostic equipment
AIUM	Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment – Jan 1998
AIUM	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices

3.0 Summary of Intended Uses

The Sonix Ultrasound Scanners is intended for use in obstetrics/gynecology, general radiology, cardiac examinations by a qualified physician, to aid in the diagnosis and evaluation of soft tissues, by generating 2 dimensional images, time motion images and biometric studies. In addition, the system can be used by a qualified physician in Emergency Medicine to assist in the decision process for triaging a patient.
The specific intended uses of this system include: abdominal, small parts, peripheral vascular, musculo-skeletal (conventional), musculo-skeletal (superficial), cephalic, small organ (breast, thyroid, testicle), trans-vaginal, trans-rectal, pediatric and fetal imaging, cardiac (adult) and cardiac (pediatric), transcranial, transesophageal, interventional.

4.0 Comparison to Predicate Device

The Sonix Ultrasound Scanner is substantially equivalent to the predicate devices with respect to intended use/indications for use, principles of operation and technological characteristics.

5.0 Technological characteristics

The technological characteristics are substantially similar to that of the predicates. The device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sounds waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, Color Flow Mapping Doppler, Power Doppler) are the same as the predicate devices identified in item 2.5. Transducer patient contact materials are biocompatible.

The beam forming architecture is very similar to that of the predicate devices. The receiving and processing hardware is similar but innovative in that it is a programmable system made of 2 building blocks, which can be reconfigured to operate the system in any imaging mode.

The parameters used to adjust image quality are the same as that seen in the predicates. This includes the use of TGC gain sliders, depth control, base control and angling, among others.

6.0 Safety considerations

As track 3 ultrasound device, the Sonix Ultrasound Scanner is designed to comply with the "Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (1992)" published by the National Electrical Manufacturers Association as UD-3.

With respect to limits on acoustic outputs, the Sonix Ultrasound Scanner complies with the guideline limits set in the September 30, 1997 revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the Sonix Ultrasound Scanner is designed to comply with IEC 601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety, and IEC 60601-2-37: Particular Requirements For The Safety Of Ultrasonic Medical Diagnostic And Monitoring Equipment.

The devices' acoustic output limits are:

I_{SPTA} (d)	720mW/cm^2
TIS/TIB/TIC	0.1 – 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
I_{SPPA} (d)	0 – 700W/cm^2 (Range)

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 4 2006

Ms. Lulia Nuca
Quality Assurance
Ultrasonix Medical Corp.
301-3480 Gilmore Way
Burnaby, BC, V5G 4Y1
CANADA

Re: K061827
Trade Name: Sonix Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 26, 2006
Received: June 28, 2006

Dear Ms. Nuca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Sonix Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

C5-2/40 convex 1/5MHz 40mm radius
C5-2/60 convex 1/5MHz 60mm radius
L14-5/38 linear 5/12MHz 38mm
L14-5W/60 linear 5/12MHz 60mm
L9-4/38 linear 4/9MHz 38mm
PA4-2/20 phased array 2/4MHz
PA7-4 phased array 4/7MHz
EC9-5/10 microconvex endocavity 5/9MHz 10mm radius
T7-4 TEE phased array 4/7MHz
4DC7-3/40 motorized convex 3/7MHz 40mm radius
C7-3/50 convex 3/7MHz 50mm radius
BPSL9-5/55/10 biplane endocavity 5/9MHz
IOT9-5/40 convex 4/7MHz 40mm radius intraoperational

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Health

Enclosure(s)

Prescription Use (Per 221 CFR 801.109)

David R. Seyman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061827

K061827

Sonix Ultrasound Scanner

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P	P	P	P	P	P (*1)	P (*2)
Intraoperative (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative Neurological		P	P	P		P	P	P	P (*1)	P (*2)
Pediatric		P	P	P	P	P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac		P	P	P	P	P	P	P	P (*1)	P (*2)
Transesophageal		P	P	P		P	P	P	P (*1)	P (*2)
Transrectal		P	P	P		P	P	P	P (*1)	P (*2)
Transvaginal		P	P	P		P	P	P	P (*1)	P (*2)
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify) (*3)		P	P	P		P	P	P	P (*1)	P (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
Intraoperative : abdominal organs and vascular
*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, live 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061827

C5-2/40 convex 1/5MHz 40mm radius transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061827

K061827

C5-2/60 convex 1/5MHz 60mm radius transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2 Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061827

K061827

L14-5/38 linear 5/12MHz 38mm transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

David R. Hyman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061827

K061827

L14-5W/60 linear 5/12MHz 60mm transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2 Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061827

K061827

L9-4/38 linear 4/9MHz 38mm transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

David A. Segner

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061827

K061827

PA4-2/20 phased array 2/4MHz transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P	P	P (*1)	P (*2)
Small Organ (specify)										
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac		P	P	P	P	P	P	P	P (*1)	P (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)		P	P	P		P	P	P	P (*1)	P (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061827

K061827

PA7-4 phased array 4/7MHz transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P	P	P (*1)	P (*2)
Small Organ (specify)										
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac		P	P	P	P	P	P	P	P (*1)	P (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)		P	P	P		P	P	P	P (*1)	P (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

David A. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061827

K061827

EC9-5/10 microconvex endocavity 5/9MHz 10mm radius transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		**P**	**P**	**P**		**P**	**P**	**P**	**P** (*1)	**P** (*2)
Transvaginal		**P**	**P**	**P**		**P**	**P**	**P**	**P** (*1)	**P** (*2)
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

David A. Seyer

(Off)

Reproductive, Abdominal,

ical Devices

ber K061827

K061827

T7-4 TEE phased array 4/7MHz transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		P	P	P		P	P	P	P (*1)	P (*2)
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

David A. Lyon

(D… Off)

D… roductive, Abdominal,

a… al Devices

…ber K061827

K061827

4DC7-3/40 motorized convex 3/7MHz 40mm radius transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2 Freehand 3D imaging, Live 3D imaging, Directional Power Doppler (DPD)

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David G. Lepper

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K061827

510(k) Number K061827

C7-3/50 convex 3/7MHz 50mm radius transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2 Freehand 3D imaging, Directional Power Doppler (DPD), imaging for guidance of biopsy

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

David A. Seguin

K061827

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Neurological Devices
K061827

BPSL9-5/55/10 biplane endocavity 5/9MHz transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P	P	P (*1)	P (*2)
Transvaginal		P	P	P		P	P	P	P (*1)	P (*2)
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 221 CFR 801.109)

David B. Legassm

...uctive, Abdominal, ... Devices K061827

K061827

IOT9-5/40 convex 4/7MHz 40mm radius intraoperational transducer

Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Intraoperative Neurological		P	P	P		P	P	P	P (*1)	P (*2)
Pediatric		P	P	P		P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P	P	P (*1)	P (*2)
Transvaginal		P	P	P		P	P	P	P (*1)	P (*2)
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Small Organ: breast, thyroid, testicle
Intraoperative : abdominal organs and vascular
*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Live 3D imaging, Directional Power Doppler (DPD)

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